PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 05 June 2001 (05.06.01)	
International application No. PCT/CA00/01004	**Applicant's or agent's file reference** 5352-91
International filing date (day/month/year) 31 August 2000 (31.08.00)	**Priority date** (day/month/year) 31 August 1999 (31.08.99)
Applicant PAWLUCZYK, Romuald et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

20 February 2001 (20.02.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Nestor Santesso
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

To:

GOWLING LAFLEUR HENDERSON LLP
Suite 2600
160 Elgin Street
Ottawa, Ontario K1P 1C3
CANADA

Date of mailing

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

Date of mailing (day/month/year)	
09 January 2002 (09.01.02)	
Applicant's or agent's file reference 5352-91	**IMPORTANT NOTIFICATION**
International application No. PCT/CA00/01004	**International filing date** (day/month/year) 31 August 2000 (31.08.00)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address	State of Nationality	State of Residence
GOWLING LAFLEUR HENDERSON LLP Suite 4900 Commerce Court West Toronto, Ontario M5L 1J3 Canada	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address	State of Nationality	State of Residence
GOWLING LAFLEUR HENDERSON LLP Suite 2600 160 Elgin Street Ottawa, Ontario K1P 1C3 Canada	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the International Preliminary Examining Authority
☐ the designated Offices concerned
☒ the elected Offices concerned
☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Marie-José DEVILLARD
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

GOWLING LAFLEUR HENDERSON LLP
Suite 4900
Commerce Court West
Toronto, Ontario M5L 1J3
CANADA

Date of mailing (day/month/year)
12 October 2001 (12.10.01)

Applicant's or agent's file reference
5352-91

IMPORTANT NOTIFICATION

International application No.
PCT/CA00/01004

International filing date (day/month/year)
31 August 2000 (31.08.00)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
BERESKIN & PARR
40 King Street West
40th Floor
Toronto, Ontario M5H 3Y2
Canada

State of Nationality:
State of Residence:
Telephone No.: (416) 364-7311
Facsimile No.: (416) 361-1398
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [X] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
GOWLING LAFLEUR HENDERSON LLP
Suite 4900
Commerce Court West
Toronto, Ontario M5L 1J3
Canada

State of Nationality:
State of Residence:
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:
The appointment of the agent of record has been revoked. A new agent has been appointed, as indicated in Box 2.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[X] other: Bereskin & Parr

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Cécile CHATEL (Fax 338.87.40)
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
5352-91		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 00/ 01004	31/08/2000	31/08/1999
Applicant		
CME TELEMETRIX INC et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [ ] the text is approved as submitted by the applicant. comment 05 Feb 01 CW

   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 3A

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 00/01004

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A compact device (10) for non-invasively monitoring concentration levels of blood constituents, including glucose, cholesterol, alcohol, blood gases and various ions. The device includes a finger receptor (140) having a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source (91) through a finger located in the channel in a direction generally normal to the finger. Certain heat generating components, including a stable power supply for the device, are external to the device housing so as to reduce heat generation and thereby increase stability of the device. The device includes a communications inferface for interacting with a computer. The device can be used for clinical use or for home use and the memory of the computer can be used to assist with record keeping and with dosage calculations.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BERESKIN & PARR
40 King Street West, 40th Floor
Toronto, Ontario M5H 3Y2
CANADA

PCT

08-891108wo

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	26.07.2001
Applicant's or agent's file reference 5352-91	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA00/01004	31/08/2000	31/08/1999

Applicant
CME TELEMETRIX INC et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Weber, R Tel.+49 89 2399-2382

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
5352-91		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA00/01004	31/08/2000	31/08/1999
International Patent Classification (IPC) or national classification and IPC A61B5/00		
Applicant CME TELEMETRIX INC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20/02/2001	26.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Meyer, F Telephone No. +49 89 2399 2233

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-11	as originally filed

Claims, No.:

1-11	as originally filed

Drawings, sheets:

1/6-6/6	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-11
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations
   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Reference is made to the following documents:

D1: US 5 361 758
D2: US 5 429 128

Re Item V

2.1. Novelty - independent claim 1:

Both **D1** and **D2** disclose a measuring device for non-invasively measuring levels of constituents in blood and tissue in a living subject (*i.e.* in the finger tip of a human being), comprising:

(a) a polychromatic light source that emits a broad spectrum of light in the near infrared range and adjacent visible light;

(b) a part receptor shaped for receiving a part (*i.e.* the finger tip) of said subject;

(c) a light receptor for collecting a continuum of wavelengths over said broad spectrum after said light has been directed onto said part;

(d) dispersion means coupled to said light receptor for dispersing said collected light into a dispersed spectrum of component wavelengths of said collected light;

(e) a photodetector coupled to said dispersion means arranged to take absorbance measurements from said dispersed spectrum and to produce a measurement signal.

The features of a communications interface connectable to an external computer arranged to communicate said measurement signal to said computer (= feature (f) in claim 1 of the present application) and of a power interface connectable to an external stabilized power source (= feature (g) in claim 1) are not disclosed in D1 or D2.

US 5 086 229 discloses (see in particular Fig.2A,2B,19 and description thereof) a measuring device for non-invasively measuring levels of constituents (*i.e.* glucose) in blood and tissue in a living subject (*i.e.* in the finger tip of a human being). The device comprises a light source that emits light at at least two discrete wavelengths in the near infrared range, a finger receptor (see feature (b) above), a photodetector (see feature (e) above), and a battery and a microprocessor connected to the light source and the detector via cables (the respective interfaces are not disclosed). The features (c) and (d) mentioned above are also

not disclosed in this document.

US 5 167 230 discloses (see in particular Fig.2,3 and description thereof) a measuring device for non-invasively measuring levels of constituents (*i.e.* the oxygenation state) in blood and tissue in a living subject (*i.e.* in the leg of a human being). The device comprises a detector unit comprised of a light source that emits light at two discrete wavelengths in the near infrared range and a photodetector (see feature (e) above), a battery pack remote from the detector unit and connected to the detector unit via cables (a power interface is not explicitly mentioned) and a radio-linked telemetry system comprised of a transmitter and a receiver (an external computer is not mentioned). The features (b), (c) and (d) mentioned above are also not disclosed in this document.

WO 92/00513 discloses (see in particular Fig.21 and description thereof) a measuring device for non-invasively measuring levels of constituents (*i.e.* glucose) in blood and tissue in a living subject (*i.e.* in the finger tip of a human being). The device comprises a light source that emits light at at least two discrete wavelengths in the near infrared range, a finger receptor (see feature (b) above), a light receptor (see feature (c) above), a photodetector (see feature (e) above), and a replaceable cartridge connectable via an interface and containing a battery and a memory. The feature of a communications interface connectable to an external computer (see feature (f) above) and also the feature (d) are not disclosed in this document.

The subject-matter of **claim 1** thus satisfies the requirements of Article 33(2) PCT.

2.2. Inventive step - independent claim 1:

Starting from D1 or D2, the **problem to be solved** by the present invention is to provide a device for non-invasively monitoring concentration levels of blood constituents, the device being compact and having improved stability and reduced sensitivity to heat.

Solution provided by the invention is a device comprising the features (a) - (g), in particular the features (f) and (g), mentioned above. Since an external power source and an external computer can be used with the device of the present invention via the respective interfaces, the heat generated by these components will no longer affect the stability and accuracy of the device.

Although documents US 5 086 229 and WO 92/00513 relate to the same field as documents D1 and D2 (*i.e.* non-invasive measurement of blood glucose level in

the finger tip of a human being), it may be doubted whether the skilled person would combine the teachings of D1 or D2 with either of US 5 086 229 or WO 92/00513, since no hint is given in US 5 086 229 or WO 92/00513 that the devices disclosed in these documents solve the posed problem. Even if the skilled person would combine the teachings of D1 or D2 with either of US 5 086 229 or WO 92/00513, he would not arrive at the subject-matter of claim 1 since none of these documents discloses a communications interface connectable to an external computer.

The subject-matter of **claim 1** thus satisfies the requirements of Article 33(3) PCT.

2.3. **Claims 2-11** are dependent on claim 1 and therefore also satisfy the requirements of Article 33(1) PCT.

Re Item VII

3.1. Independent **claim 1** is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (D1 or D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features, *i.e.* features (f) and (g), being included in the characterising part (Rule 6.3(b)(ii) PCT).

3.2. The features of the claims are not provided with reference numerals placed in parentheses (Rule 6.2(b) PCT).

3.3. On p.6 l.17, the reference "'578" is not clear since in the preceding no document with a publication number ending on 578 has been cited.

3.4. The passage on p.11 l.29-32 is superfluous and should hence have been deleted.

3.5. In the description on p.4 l.33 and on p.8 l.11-12, the applicant incorporates by reference the disclosure of two US patents. If the applicant has the opinion, that the said disclosure contains matter which is essential for carrying out the invention as meant by Article 5 PCT, the applicant should expressly incorporate this matter into the description. Otherwise, this passage should be deleted from the description (see the PCT Guidelines II 4.17).

Re Item VIII

4. The application does not meet the requirements of Article 6 PCT, because the claims are not clear.

4.1. Although the expressions in **claim 1** "a broad spectrum" (p.12 l.6), which comprises a relative term with no well-known meaning in the art, and "in the near infrared range and adjacent visible light" (p.12 l.7-8), which does not clearly define the intended wavelength range, obscure the scope of the claim, these expressions can be retained in the claim, since these expressions are not essential having regard to the invention (see paragraph 3.1. above; see also the PCT Guidelines III 4.5).

4.2. The applicants attention shall also be drawn on the fact that, due to the wording used, the phrase "said light source can be activated and light from said light source can be directed onto said part" in **claim 1** (p.12 l.12-13) does not appear to have any limiting effect on the claimed subject-matter.

4.3. The features "means for taking absorbance measurements ... and producing a measurement signal" (p.12 l.20-22) and "... for communicating said measurement signal to said computer" (P.12 l.24-25) in the apparatus **claim 1** relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT. What was meant appears to be "means arranged to take absorbance measurements ... and to produce a measurement signal" and "... arranged to communicate said measurement signal to said computer", respectively.
Similar objections are raised for the features "said device is provided in combination with ..." (p.12 l.33-34), "said external computer controls ..." (p.12 l.35) in **claim 3** and "said hand support receives the palm of a human hand" (p.13 l.31-32) in **claim 11**.

4.4. **Claim 2** does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not defined. The claim attempts to define the subject-

matter in terms of another apparatus ("is connected to the external stabilized power source", p.12 l.30) that is not part of the claimed subject-matter (see the PCT Guidelines III 4.8a).
The same applies to **claim 3** ("... is provided in combination with such said external computer" p.12 l.33-34; "wherein said external computer controls ...", p.12 l.34-35; "said computer including ...", p.13 l.1-2), to **claim 5** ("said external computer includes ...", p.13 l.8-9), to **claim 6** ("said external computer includes ...", p. l.) and to **claim 7** ("said external stabilized power source is provided by said external computer", p.13 l.17-18).

4.5. The features "said compact measuring device" in **claim 3** and "the top of said opening" in **claim 11** lack antecedence.

4.6. In **claims 5 and 6**, the difference between a "memory" and a "storage" is not at all clear and it is not clear what the function of the feature expressed by the vague term "software means" could be.

4.7. In **claim 6** it is furthermore not clear what is meant by the term "dosage information".

4.8. **Claim 9** is obscure, since a device cannot be defined with respect to the sample to be investigated ("said part received ... is a human finger", p.13 l.23-24).

Rec'd Jan 10/01

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
BERESKIN & PARR
Attn. BERESKIN & PARR
40 King Street West, 40th Floor
Toronto, Ontario M5H 3Y2
CANADA

Date of mailing *(day/month/year)* 05/01/2001	
Applicant's or agent's file reference 5352-91	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/CA 00/ 01004	International filing date *(day/month/year)* 31/08/2000
Applicant CME TELEMETRIX INC et al.	

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19: Ddent 5MAR01 cw
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Christine Voigt

Form PCT/ISA/220 (July 1998)

NOTES [redacted]ORM PCT/ISA/220 [redacted]

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 March 2001 (08.03.2001)

PCT

(10) International Publication Number
WO 01/15595 A1

(51) International Patent Classification[7]: A61B 5/00, G01N 21/31, 21/35

(21) International Application Number: PCT/CA00/01004

(22) International Filing Date: 31 August 2000 (31.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/151,538 31 August 1999 (31.08.1999) US

(71) Applicant *(for all designated States except US)*: **CME TELEMETRIX INC** [CA/CA]; 560 Parkside Drive, Waterloo, Ontario N2L 5Z4 (CA).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **PAWLUCZYK, Romuald** [CA/CA]; 362 Roselawn Place, Waterloo, Ontario N2L 5P1 (CA). **MACINTYRE, Duncan** [CA/CA]; 120 Crawford Cescent, Campbellville, Ontario L0P 1B0 (CA). **BEDNARZ, Bronislaw** [CA/CA]; 832 Royal York Road, Toronto, Ontario M8Y 2T9 (CA).

(74) Agent: **BERESKIN & PARR**; 40 King Street West, 40th Floor, Toronto, Ontario M5H 3Y2 (CA).

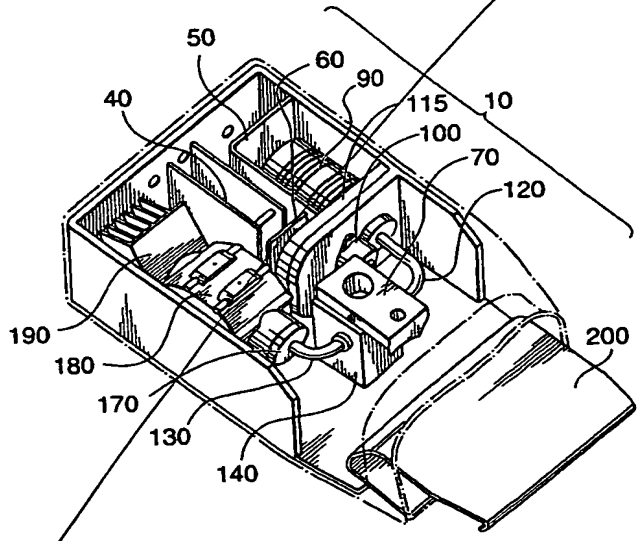
(81) Designated States *(national)*: CA, JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPACT DEVICE FOR MEASURING TISSUE ANALYTES



(57) Abstract: A compact device (10) for non-invasively monitoring concentration levels of blood constituents, including glucose, cholesterol, alcohol, blood gases and various ions. The device includes a finger receptor (140) having a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source (91) through a finger located in the channel in a direction generally normal to the finger. Certain heat generating components, including a stable power supply for the device, are external to the device housing so as to reduce heat generation and thereby increase stability of the device. The device includes a communications interface for interacting with a computer. The device can be used for clinical use or for home use and the memory of the computer can be used to assist with record keeping and with dosage calculations.

WO 01/15595 A1

INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted] 00/01004

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 G01N21/31 G01N21/35

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 361 758 A (HALL JEFFREY W ET AL) 8 November 1994 (1994-11-08) cited in the application column 3, line 52 -column 4, line 58; figure 1 ---	1,5,6,8, 9
A	US 5 429 128 A (CADELL THEODORE E ET AL) 4 July 1995 (1995-07-04) cited in the application column 2, line 4-21 column 3, line 28-53; figure 1 ---	1,8,10
A	US 5 086 229 A (MACKIE LINDA H ET AL) 4 February 1992 (1992-02-04) column 2, line 51-61 column 4, line 41 -column 6, line 16 column 7, line 1 -column 8, line 19 column 14, line 6-55; figures 2A,2B,19 --- -/--	1-3,7,8

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 December 2000	05/01/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Meyer, F

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted] 00/01004

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 167 230 A (CHANCE BRITTON) 1 December 1992 (1992-12-01) column 2, line 38-65 column 3, line 41 -column 5, line 4 column 5, line 59-63; figures 2,3 abstract	1
A	WO 92 00513 A (FUTREX INC) 9 January 1992 (1992-01-09) page 40, line 26 -page 42, line 13; figure 21	1,2,5-7

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PC[redacted] 00/01004

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5361758	A	08-11-1994	NONE		
US 5429128	A	04-07-1995	AU	8411691 A	30-03-1992
			WO	9203965 A	19-03-1992
			EP	0545987 A	16-06-1993
			JP	6503728 T	28-04-1994
			DE	69117517 D	04-04-1996
			DE	69117517 T	12-09-1996
US 5086229	A	04-02-1992	US	5028787 A	02-07-1991
			AT	145988 T	15-12-1996
			AU	8238791 A	23-01-1992
			CA	2086019 A,C	28-12-1991
			DE	69123448 D	16-01-1997
			DE	69123448 T	22-05-1997
			EP	0536304 A	14-04-1993
			IE	77034 B	19-11-1997
			JP	5508336 T	25-11-1993
			NZ	238717 A	26-08-1994
			US	5576544 A	19-11-1996
			WO	9200513 A	09-01-1992
			US	5362966 A	08-11-1994
			US	5436455 A	25-07-1995
			US	6066847 A	23-05-2000
			US	5438201 A	01-08-1995
			US	5574283 A	12-11-1996
			US	5077476 A	31-12-1991
			US	5204532 A	20-04-1993
			US	5218207 A	08-06-1993
			US	5237178 A	17-08-1993
			US	5365066 A	15-11-1994
			ZA	9104977 A	29-04-1992
			AT	163844 T	15-03-1998
			AU	5042190 A	13-08-1990
			CA	2045599 A,C	20-07-1990
			DE	69032126 D	16-04-1998
			DE	69032126 T	15-10-1998
			EP	0456716 A	21-11-1991
			ES	2114860 T	16-06-1998
			JP	2191434 A	27-07-1990
			JP	5058735 B	27-08-1993
			KR	145695 B	01-08-1998
			WO	9007905 A	26-07-1990
			US	5068536 A	26-11-1991
US 5167230	A	01-12-1992	CA	1331483 A	16-08-1994
			DE	68928348 D	30-10-1997
			DE	68928348 T	16-04-1998
			EP	0441791 A	21-08-1991
			JP	2603350 B	23-04-1997
			JP	4502563 T	14-05-1992
			WO	9004941 A	17-05-1990
			US	5779631 A	14-07-1998
			US	6134460 A	17-10-2000
WO 9200513	A	09-01-1992	US	5086229 A	04-02-1992
			US	5077476 A	31-12-1991
			US	5068536 A	26-11-1991

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/ 00/01004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9200513 A		AT 145988 T	15-12-1996
		AU 8238791 A	23-01-1992
		CA 2086019 A,C	28-12-1991
		DE 69123448 D	16-01-1997
		DE 69123448 T	22-05-1997
		EP 0536304 A	14-04-1993
		IE 77034 B	19-11-1997
		JP 5508336 T	25-11-1993
		NZ 238717 A	26-08-1994
		US 5576544 A	19-11-1996
		US 5362966 A	08-11-1994
		US 5436455 A	25-07-1995
		US 6066847 A	23-05-2000
		US 5438201 A	01-08-1995
		US 5574283 A	12-11-1996
		US 5204532 A	20-04-1993
		US 5218207 A	08-06-1993
		US 5237178 A	17-08-1993
		US 5365066 A	15-11-1994
		ZA 9104977 A	29-04-1992

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 March 2001 (08.03.2001)

PCT

(10) International Publication Number
WO 01/15595 A1

(51) International Patent Classification[7]: A61B 5/00, G01N 21/31, 21/35

(21) International Application Number: PCT/CA00/01004

(22) International Filing Date: 31 August 2000 (31.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/151,538 31 August 1999 (31.08.1999) US

(71) Applicant *(for all designated States except US)*: **CME TELEMETRIX INC** [CA/CA]; 560 Parkside Drive, Waterloo, Ontario N2L 5Z4 (CA).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **PAWLUCZYK, Romuald** [CA/CA]; 362 Roselawn Place, Waterloo, Ontario N2L 5P1 (CA). **MACINTYRE, Duncan** [CA/CA]; 120 Crawford Cescent, Campbellville, Ontario L0P 1B0 (CA). **BEDNARZ, Bronislaw** [CA/CA]; 832 Royal York Road, Toronto, Ontario M8Y 2T9 (CA).

(74) Agent: **BERESKIN & PARR**; 40 King Street West, 40th Floor, Toronto, Ontario M5H 3Y2 (CA).

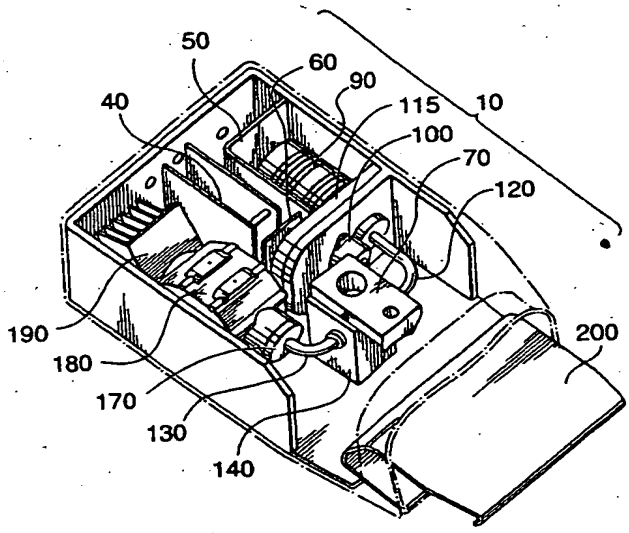
(81) Designated States *(national)*: CA, JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPACT DEVICE FOR MEASURING TISSUE ANALYTES



(57) Abstract: A compact device (10) for non-invasively monitoring concentration levels of blood constituents, including glucose, cholesterol, alcohol, blood gases and various ions. The device includes a finger receptor (140) having a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source (91) through a finger located in the channel in a direction generally normal to the finger. Certain heat generating components, including a stable power supply for the device, are external to the device housing so as to reduce heat generation and thereby increase stability of the device. The device includes a communications interface for interacting with a computer. The device can be used for clinical use or for home use and the memory of the computer can be used to assist with record keeping and with dosage calculations.

WO 01/15595 A1

Title: COMPACT DEVICE FOR MEASURING TISSUE ANALYTES

FIELD OF THE INVENTION

This invention relates to a compact device for non-invasively measuring concentration levels of blood constituents. The device includes a communications interface for interacting with a computer.

BACKGROUND OF THE INVENTION

Invasive techniques of measuring blood constituents are in common usage. These techniques are painful, potentially dangerous and expensive to operate. The normal procedure is to obtain a blood sample from a vein and this sample is then tested in a medical laboratory, using a number of chemical procedures to measure each constituent separately. Alternatively, home glucose testing uses a finger puncture that is spotted onto an enzyme-based semi-permeable membrane test strip and is allowed to react for a certain length of time, with insulin administration then based upon either a visual color comparison with a standard color chart or by means of a more accurate and unambiguous spectroscopic technique (for example by measurement and comparison of reflectance at several wavelengths). There is a risk of infection and sometimes a patient can develop a rash when these invasive techniques are used.

Previous devices for non-invasively monitoring concentrations of blood constituents of a patient are also known. These devices are used to externally measure either the concentration of the constituent in gases emitted by the body; the concentration contained in perspiration; or the concentration contained in body fluids such as tears, saliva, or urine samples; or, alternatively, the blood constituent is measured using radiation passed through a part of the patient's body such as the earlobe or finger.

A recently developed and patented non-invasive method and device is described in U.S. Patent No. 5,361,758. '758 discloses a non-invasive method and device for monitoring the concentration levels of one particular constituent or, alternatively, of measuring the concentration level of several different constituents simultaneously, the method and device producing results in a short time period that are highly accurate and compare favorably to invasive techniques.

Specifically, the non-invasive device and method disclosed in '758 measures concentration levels of blood and tissue constituents in a living subject such as a human or animal utilizing a polychromatic light source that emits light over a broad spectrum of wavelengths in the near infrared range. The light is passed through, or reflected from, a part of the subject such as a finger, ear lobe or other part of the body. That light is then separated into its various components by means of a grating or prism, and the near infrared band is focussed onto a linear array detector. A microprocessor uses the output of the array detector to measure the transported light (scattered light and possibly transmitted light), calculate the equivalent absorbance, and calculate the second derivative of the equivalent absorbance. A calibration equation is used for each constituent to be monitored to convert the second derivative measurements to a concentration level for that constituent. The device can be used to determine levels of various blood and tissue constituents, including glucose, cholesterol, alcohol, blood gases and various ions.

A finger receptor for use with a non-invasive monitoring device such as the one described '758 is disclosed in U.S. Patent No. 5,429,128. The finger receptor disclosed in '128 has a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source through a finger located in the channel in a direction generally normal to the finger. Extraneous light is excluded and the finger is held in position by a spring-mounted roller. The receptor has sensing means to determine when a finger has been properly positioned in the channel.

While the method and devices disclosed in '758 and '128 provide a significantly improved and effective non-invasive technique for monitoring the concentration of known constituents in blood or tissue, there is a need for a device which is compact, efficient and portable, and which has improved stability and less sensitivity to problems created by heat.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a device for non-invasively monitoring concentration levels of blood constituents, the device being compact and efficient, and having improved stability and reduced sensitivity to heat. The device includes a communications

interface for interacting with a computer and draws power from a stable external power supply.

In one aspect, the present invention provides a measuring device for non-invasively measuring levels of constituents in blood and tissue in a living subject such as a human or animal, said measuring device comprising:

(a) a polychromatic light source that emits a broad spectrum of light in the near infrared range and adjacent visible light;

(b) a part receptor shaped for receiving a part of said subject, said part receptor being located relative to said light source so that when part of said subject is placed in the part receptor, said light source can be activated and light from said light source can be directed onto said part;

(c) a light receptor for collecting a continuum of wavelengths over said broad spectrum after said light has been directed onto said part;

(d) dispersion means coupled to said light receptor for dispersing said collected light into a dispersed spectrum of component wavelengths of said collected light;

(e) a photodetector coupled to said dispersion means for taking absorbance measurements from said dispersed spectrum and producing a measurement signal;

(f) a communications interface connectable to an external computer for communicating said measurement signal to said computer; and

(g) a power interface connectable to an external stabilized power source.

Preferably, the polychromatic light source is connected to the external stabilized power source through said power interface.

More preferably, the external computer controls at least one function of said compact measuring device, said computer including means for receiving said measurement signal.

More preferably, the device further includes an analog to digital converter for converting said measurement signal into a digital measurement signal for communication to said computer.

Preferably, the external computer includes a memory, a storage, and software means for storing a plurality of said measurement signals for a plurality of measurements.

Also preferably, the external computer includes a memory, a storage, and software means for storing, retrieving and displaying dosage information corresponding to measurement signals received by said computer from said device.

More preferably, the external stabilized power source is provided by said external computer.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings which show a preferred embodiment of the present invention, in which:

FIG. 1 is a block diagram showing the relationships for various components of a device for non-invasively monitoring the concentration levels of blood constituents;

FIG. 2 is a perspective view of one embodiment of a device in accordance with the present invention;

FIG. 3A is another perspective view of the device of FIG. 2 showing some of the internal components of the device;

FIG. 3B is an exploded view of the device of FIG. 2, also showing the internal components of FIG. 3A;

FIG. 3C shows a schematic view of some of the main components of the device shown in FIGS. 3A and 3B; and

FIG. 4 is a block diagram showing the relationships between the device of FIGS. 2, 3A-3C and a computer system.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

As noted above, this invention relates to a compact device for non-invasively measuring concentration levels of blood constituents.

The basic principles of operation of the non-invasive measurement technique used in the present invention is provided in U.S. Patent No. 5,361,758 which is incorporated herein by this reference.

'758 discloses that a near infrared region of the electromagnetic spectrum is particularly well-suited to in vivo diagnostic applications because human tissue is essentially transparent to the incident radiation

and therefore sufficient penetration of the radiation is possible to allow accurate quantitative analysis.

As shown in FIG. 1, a prior art non-invasive device for continuously monitoring concentration levels of blood and tissue constituents has a polychromatic light source. '758 discloses that the light source can emit light over a very wide bandwidth including light in the near infrared spectrum. (It has been recognized by the inventor that adjacent visible light outside of the range specified in '758 also contributes information for in vivo diagnostic applications.) The light from the light source passes first through a collimator, which is a collection of lenses that concentrate the light into a narrow parallel beam directed at the receptor. The receptor is shaped to receive within it a part of the subject, for example, a finger or ear of a human. The light is directed onto the finger or ear and is scattered and attenuated by the finger or ear. The scattered and attenuated light is collected by lenses and directed through a slit to diffraction means. Preferably, the diffraction means is a diffraction grating, possibly produced with holographic method. The light from the grating is dispersed into its component wavelengths so that it falls along the length of a linear array detector. The array detector has a series of photosensitive elements, which are electronically scanned by a microprocessor to measure the intensity of light for each wavelength transmitted through or reflected from the tissue in the receptor. The detector is connected to the microprocessor, producing an output spectrum, with the microprocessor analyzing the measurements and ultimately producing a result for each concentration level determined. The result can be shown on a display and/or printed on a printer. The keyboard allows a user to control the device, for example, to specify a particular constituent to be measured. The timing and control is activated by the microprocessor to control the device, for example, to determine number and timing of measurements.

It is disclosed in '758 that the polychromatic light source can be a tungsten-halogen bulb and is powered by a stabilized power source, for example, a DC power supply, or by a battery. (The inventors have realized that photoluminescent sources of radiation may also be used.) This polychromatic light source may be a tungsten-halogen lamp or it may be a collection of LEDs or other light sources selected to emit

radiation in the near infrared region (and adjacent visible light, as realized by the inventors). It should be noted that after activation of the light source, the scanning detector is read so that light is passed through the receptor and measured by the detector through the taking of a series of measurements at a selected wavelength.

In the system disclosed in '758, the microprocessor control activates and scans the linear array detector only after a detected pulse has occurred and the full spectrum measurements are then taken for the light after it passes through the receptor. Scanning is stopped when another pulse is detected on the selected wavelength. In other words, measurements are taken only when the blood pressure in the finger or ear or other part of the person is at a constant level.

In contrast, in the present invention, measurements are taken over some phase of a pulse, or are taken over several pulses, and an average of the resulting signal over the measurement period is calculated.

It is explained in '578 that in a further variation, the device can take all measurements regardless of the pulse of the subject. The microprocessor can then be controlled by computer software to select those measurements that are taken between pulses and to base the calculation of the concentration levels on the selected measurements. In a further variation, the measurements upon which the results are based, could be taken during pulses.

It is explained in '758 that the receptor has means for eliminating extraneous light. For example, where a finger is the part of a human through which the light passes, the receptor has an oblong shape similar to but larger than the shape of the finger. The means for eliminating extraneous light from the receptor is a flexible ring that surrounds an entrance to the receptor. When the finger is inserted, the flexible ring forms a seal around the finger when the finger has been inserted into the receptor. All surfaces within the device, including surfaces within the receptor are made non-reflective to minimize stray light. (The flexible ring forming the seal is optional and is not used in the present invention. However, measures have been taken to minimize stray light, as discussed further below.)

Finally, '758 discloses that, after the measurements are taken with a finger of the subject in place in the finger receptor, a reference set of measurements is taken of the incident light, being the light generated in the device when no part of the subject is in contact with the receptor. A ratio of the two measurements is then calculated.

Based on the principles of operation of a non-invasive monitoring device summarized above and disclosed in detail in '758, a new and improved compact device for non-invasively monitoring the concentration levels of blood constituents is shown in FIG. 2 and generally referred to by reference numeral 10. FIG. 2 shows an external perspective view of the device 10 with an instrument cover or housing 20 and a hand support 200, and shows an opening 11 into which the hand of a user is inserted for taking a measurement of the user's blood or tissue constituents. Optional legs 210 allows the device 10 to sit in position on a flat surface.

Now referring to FIGS. 3A -3C, and referring back to FIG. 1, there is provided a polychromatic light source which may comprise a lamp 91 (FIG. 3C) within a lamp housing or reflector 94 (FIGS. 3A and 3B). The light source or lamp 91 in FIGS. 3A and 3B is able to generate light over a wide bandwidth including the near infrared regions, discussed earlier, and further including adjacent visible light.

While the '758 patent discloses the use of a collimator (FIG. 1) which uses a series of lenses to concentrate the light from the polychromatic light source into a narrow parallel beam, the present invention uses an elliptical reflector 94 to reflect and concentrate the light from the polychromatic light source or lamp 91. A heat reflection filter 95 is provided within the elliptical reflector 94 to contain heat generated by the lamp 91.

Still referring to FIGS. 3A-3C, a multi-positional shutter 101 is provided between the lamp 91 and the first light guide 120 to further control the light entering the first light guide 120, or otherwise filtering, attenuating, or blocking the light entering the first light guide 120. A stepping motor 100 is provided for rotating the multi-positional shutter 101 into one of a plurality of rotational positions. In one position, the multi-positional shutter 101 provides an opening 102 to allow light concentrated by the elliptical reflector into a first light guide 120. In

another position, a plurality of very small holes 103 are provided to allow some of the light from the light source 91 to enter the first light guide 120. In yet another position, a filter 104 is provided which attenuates the light from the light source 91 entering the first light guide 120. In yet another position 105, the multi-positional shutter 101 entirely blocks the light from the light source 91. Various other means of attenuating or otherwise controlling the light entering the first light guide 120 may be provided on the multi-positional shutter 101.

Still referring to FIGS. 3A-3C, a the first light guide 120 guides the beam of light to a finger receptor 70, 140. The operation of the finger receptor 70, 140 is described in detail in U.S. Patent 5,429,128 which is incorporated herein by this reference. As disclosed in '128, the finger receptor 70, 140 receives a finger of a user into a channel, and the beam of light guided by the first light guide 120 is directed generally normally to the finger inserted into the finger receptor 70, 140. As further disclosed in '128, and described above, the finger receptor 70,140 includes a sensing means to determine when a finger had been properly positioned in the channel and acts to exclude extraneous light which would interfere with the signal received by the light receptor (FIG. 1).

In order to further reduce the amount of extraneous light entering the light receptor (FIG. 1), the device cover 20 has been designed to substantially cover the finger receptor and other components within the device housing 20, 30. Referring back to FIG. 2, preferably, the hand support 200 may be adjustable preferably in a vertical direction so as to adjust the size of the opening 11 to accommodate hands of different size. Also, the top of the opening 11 may be shaped to generally fit the profile of a human hand across the top of the hand, so that extraneous light entering the housing 20 is minimized. It will also be appreciated that the edges of the opening 11 may be somewhat flexible to better fit the shape of an inserted hand.

Light which passes through the finger receptor 70, 140 is received by a light receptor (FIG. 1) which in FIGS. 3A and 3B comprises a second light guide 130 which guides light to a light guide adapter 170 and to a spectroscope 180. The light is then detected by a thermostabalized and/or cooled photodetector array assembly 190 which includes a photodetector array 191, electronics 192A to control a thermoelectric

cooler and electronics 192B to digitize the signal received by the photodetector array 191, and a heat sink 193 including a thermoelectric cooler to dissipate heat.

Preferably, the electronics in the photodetector array assembly 190 provides analog to digital conversion of the light signal received by the photodetector array 190 for transmission to a computer. Sending an analog signal to a computer for processing and conversion is less preferred since an analog signal is more susceptible to electromagnetic interference. As explained earlier, the device 10 shown and described in FIGS. 3A and 3B (and shown in block diagram form in FIG. 1) requires stable operating conditions to function optimally. One component which is important to stability of the device 10 is a stable power supply with a large power reserve.

In previous devices, such a power supply is typically provided within the device, and the heat generated by the power supply and other internal components has the potential to affect the stability and accuracy of the device.

In order to provide a compact, high-performance device with improved stability, the device 10 shown and described in FIGS. 2 to 4 operates on a power supply which is external to the device 10. As the device 10 is designed to interface with a computer 300 ((FIG. 4), preferably, the device 10 will draw power from the computer power supply 310. A power conditioner 311 may be provided between the computer power supply 310 and the device 10 in order to provide a stable, clean power source for the device 10.

Referring back to FIGS. 3A-3C, the component which will generate the most heat within the device is the lamp within the lamp housing 90. In order to minimize the effect of the heat generated by the lamp and lamp housing 90, a lamp heat screen 50 is provided between the lamp housing 90 and the other components in the device, including the electronics 40, the spectroscope 180 and the photodetector array 190. Furthermore, an electronics board 60 to control the multi-positional shutter 101 also provides a shield to the electronics 40 from the heat conducted by the multi-positional shutter housing 115 from the lamp 91.

Advantageously, by shielding the heat generating lamp housing 90 from the other components in the device, and by removing the

power supply so that the power supply is external to the device (preferably the computer power supply 310), the heat generated within the device housing 20, 30 is significantly reduced. Heat which is produced within the housing 20, 30 is dissipated by the heat sink provided with the photodetector array 190 and is also removed from the device housing 20, 30 by means of cooling fans 150 and 160 and vents 21.

As a result of the heat generated in the housing 20, 30 being significantly reduced, and as a result of the reduced electronic noise in the electronic circuits in the device 10, a less powerful light source can be used in the device 10. That is, the lamp (tungsten-halogen lamp) used for the light source may be less powerful while the same level of measurement sensitivity is retained (because of the lower noise level in the electronic circuits) as compared to a device with an internal power supply.

Also, by allowing the computer 300 (FIG. 4) interconnected to the device 10 to process many of the control functions for the device 10, the electronics 40 required within the device 10 can be minimized to basic control and communications functions. In effect, the device 10 may then be operated as if it was a peripheral device to a computer, with the main function of the device 10 being for providing a light source, a light receptor, and providing raw data resulting from the measurement for further processing.

In a preferred embodiment, the device 10 is interconnected to a computer by means of a customized computer interface card 320. For example, the computer interface card 320 may be built to interconnect with an industry standard PCI (Peripheral Circuit Interconnect) bus or an ISA (industry standard architecture) bus, both of which are common to many personal computer systems presently available, or any other bus developed for computer interface in the future. For use with a portable laptop computer system, a suitable customized computer interface card may be developed to the PCMCIA industry standard. The computer interface card 320 may receive analog data from the device 10 and covert the analog signal to a digital signal for processing by the computer 300.

A connection for the device 10 via other industry standard interfaces such as parallel or serial ports, SCSI and USB ports is also

possible, although such options may require additional electronics to be placed within the device housing 20, 30 and thus increase the heat generation within the device 10. Nevertheless, a benefit of such a connection to a parallel, serial, SCSI or USB port is that the installation of a card into a computer may not be required.

As explained, the interconnection of the device 10 to a computer 300 facilitates controlling the device 10 using software means running in memory 330 and the microprocessor 340 and optionally stored in storage 380 in the computer 300. Furthermore, the software means may provide a user with a graphical user interface on a suitable display 350 including step-by-step instructions for operating the device 10.

The software means may also control receiving and analyzing data collected by the device 10 and may display measurement results graphically on the computer display 350 or optionally print out the results on a printer 355. A series of results may be stored in storage 380 for further processing or recall. The device 10 may be controlled by means of an input, such as a keyboard 360 or a mouse 370, among many other possible input devices.

In summary, by generally limiting the device 10 to the essential components for providing a light source, and measuring the light which passes through a finger placed in the finger receptor 70, 140, the device 10 is significantly reduced in size and cost. Also, by significantly reducing the heat generated in the device, cooling requirements are reduced and the device 10 is less sensitive to heating problems, thereby improving the stability and accuracy of the device. Also, by transferring the control interface and analysis onto a computer 300, the processing power of the computer 300 is used to enhance the user interface and to enhance analysis of the raw data collected by the device 10.

While one embodiment of a device according to the present invention has been shown and described, it will be appreciated that changes and modifications are possible without departing from the scope of the invention which is defined by the following claims.

WE CLAIM:

1. A measuring device for non-invasively measuring levels of constituents in blood and tissue in a living subject such as a human or animal, said measuring device comprising:

(a) a polychromatic light source that emits a broad spectrum of light in the near infrared range and adjacent visible light;

(b) a part receptor shaped for receiving a part of said subject, said part receptor being located relative to said light source so that when part of said subject is placed in the part receptor, said light source can be activated and light from said light source can be directed onto said part;

(c) a light receptor for collecting a continuum of wavelengths over said broad spectrum after said light has been directed onto said part;

(d) dispersion means coupled to said light receptor for dispersing said collected light into a dispersed spectrum of component wavelengths of said collected light;

(e) a photodetector coupled to said dispersion means for taking absorbance measurements from said dispersed spectrum and producing a measurement signal;

(f) a communications interface connectable to an external computer for communicating said measurement signal to said computer; and

(g) a power interface connectable to an external stabilized power source.

2. The device in claim 1, wherein, said polychromatic light source is connected to the external stabilized power source through said power interface.

3. The device in claim 1, wherein said device is provided in combination with such said external computer, and wherein said external computer controls at least one function of said compact

measuring device, said computer including means for receiving said measurement signal.

4. The device in claim 3, further comprising an analog to digital converter for converting said measurement signal into a digital measurement signal for communication to said computer.

5. The device in claim 3, wherein, said external computer includes a memory, a storage, and software means for storing a plurality of said measurement signals for a plurality of measurements.

6. The device in claim 3, wherein, said external computer includes a memory, a storage, and software means for storing, retrieving and displaying dosage information corresponding to measurement signals received by said computer from said device.

7. The device in claim 3, wherein, said external stabilized power source is provided by said external computer.

8. The device in claim 1, wherein, said part receptor is shaped to receive said part in close alignment, so as to reduce extraneous light.

9. The device in claim 8, wherein, said part received within said part receptor is a human finger, and the device has a housing with an opening adapted to receive a human hand.

10. The device in claim 9, further comprising a hand support at the housing opening, said hand support being adjustable to vary the size of the opening.

11. The device in claim 10, wherein, said hand support receives the palm of a human hand and the top of said opening is curved to generally fit the profile of a human hand across the top of the hand.

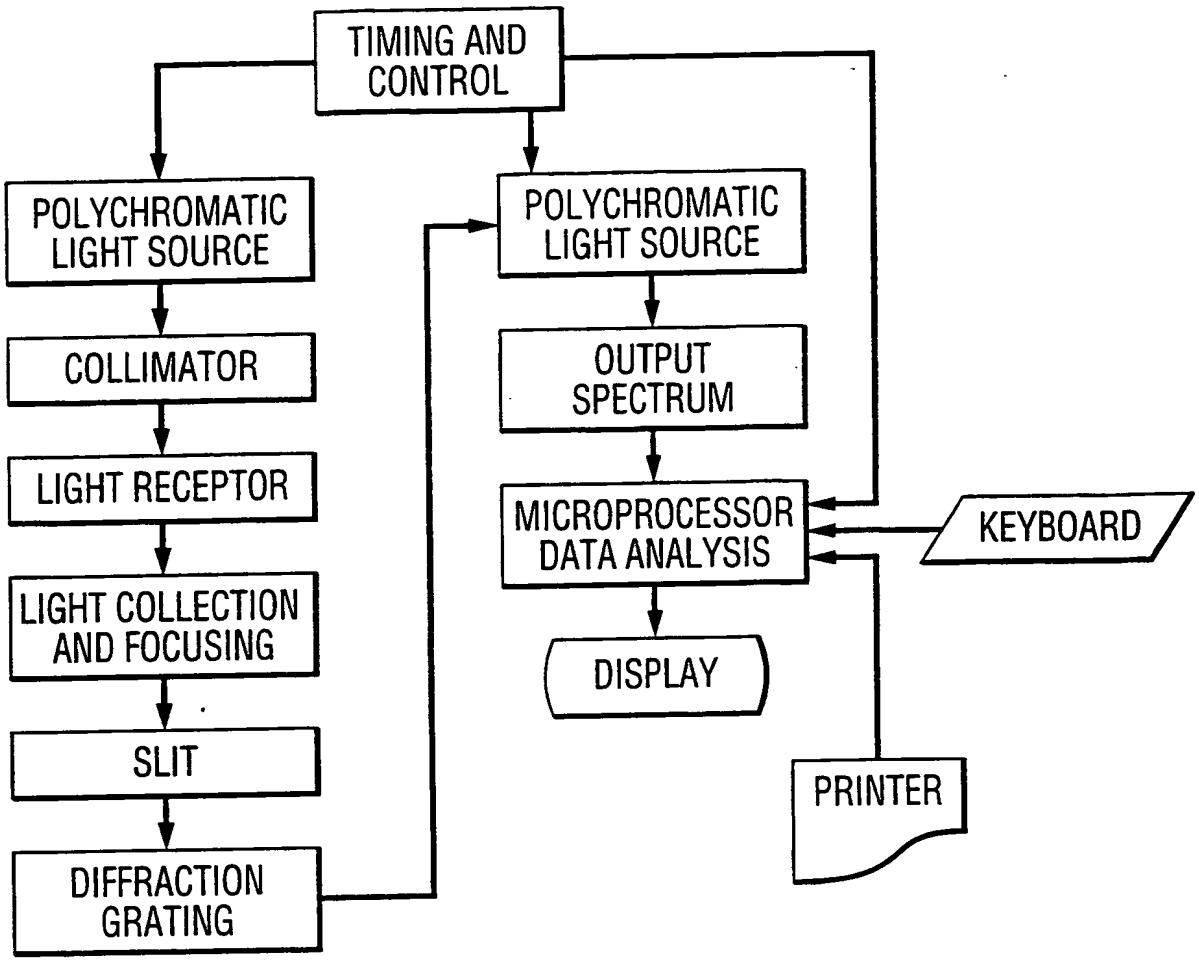


FIGURE 1
PRIOR ART

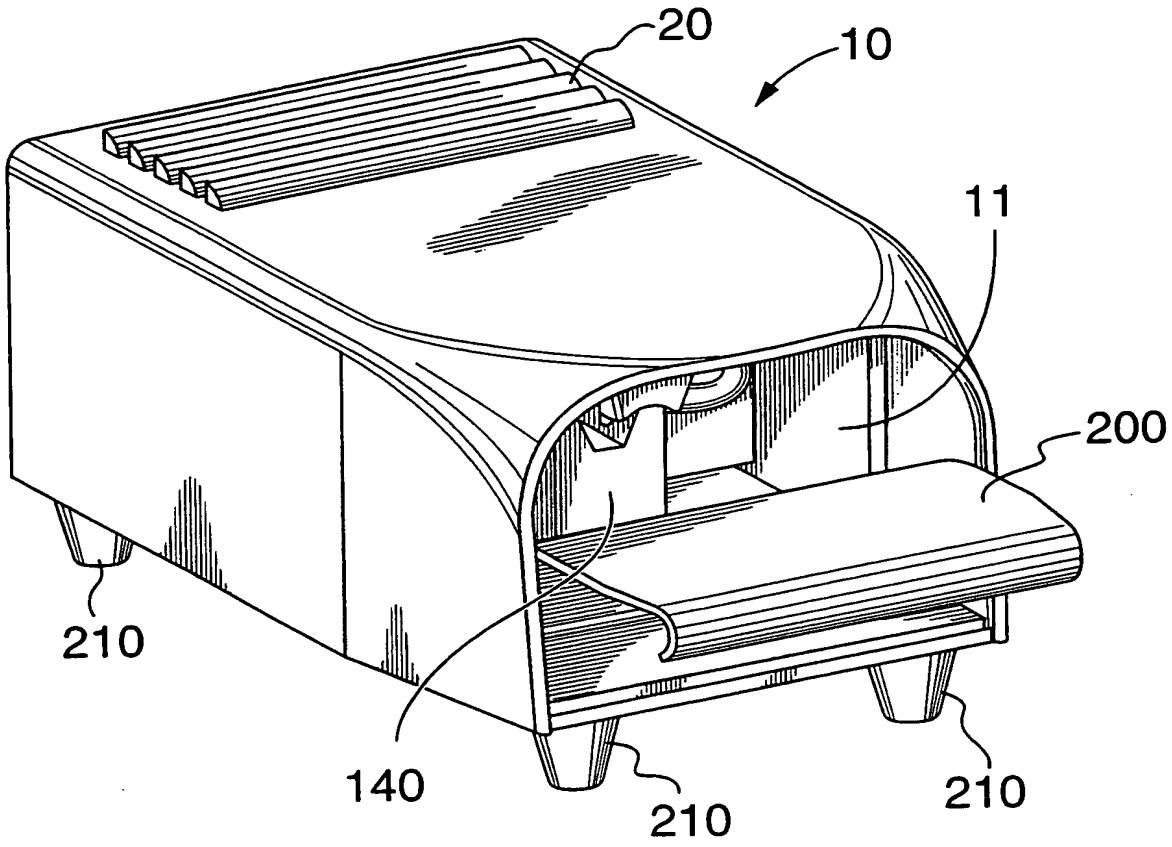


FIGURE 2

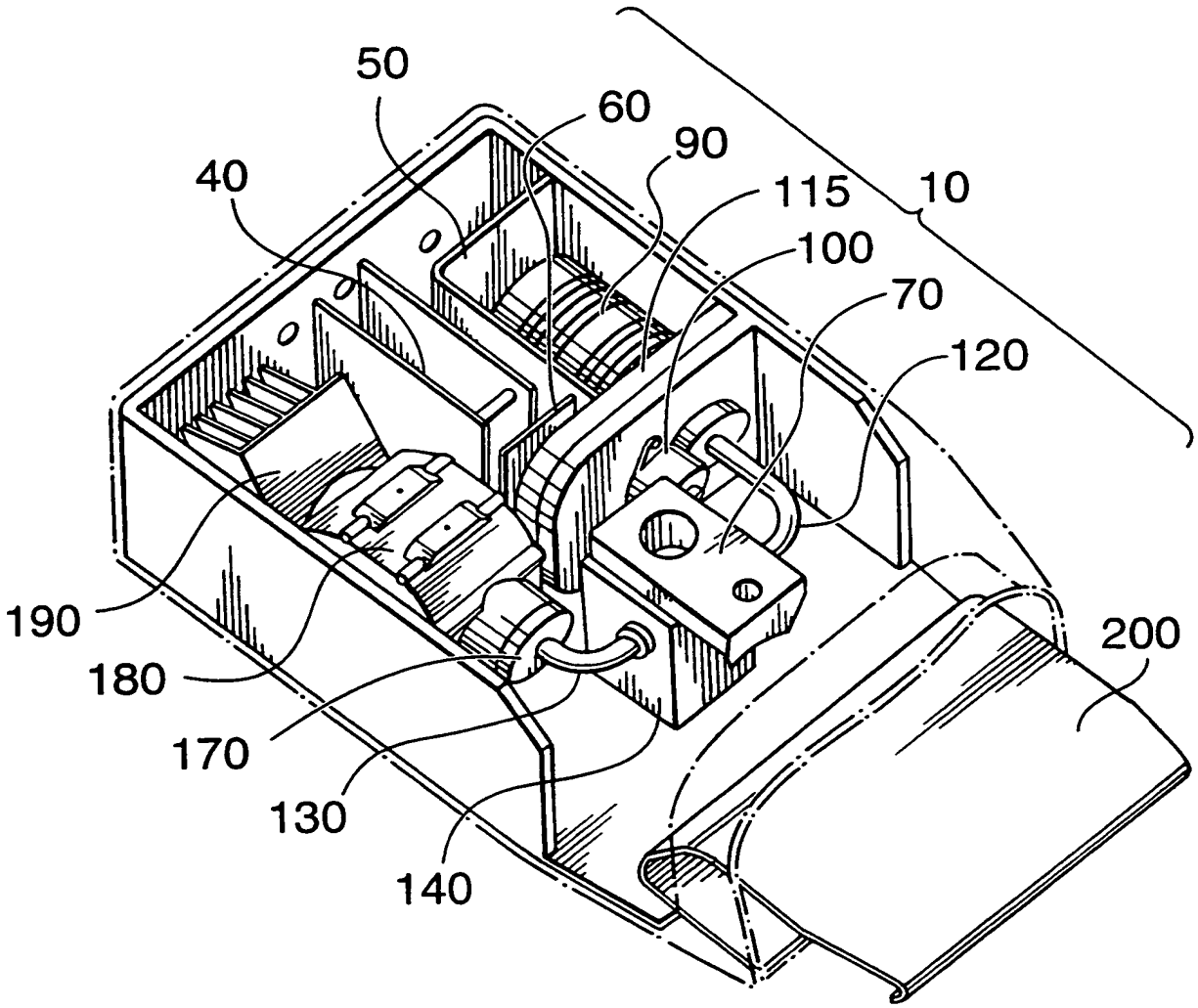


FIGURE 3A

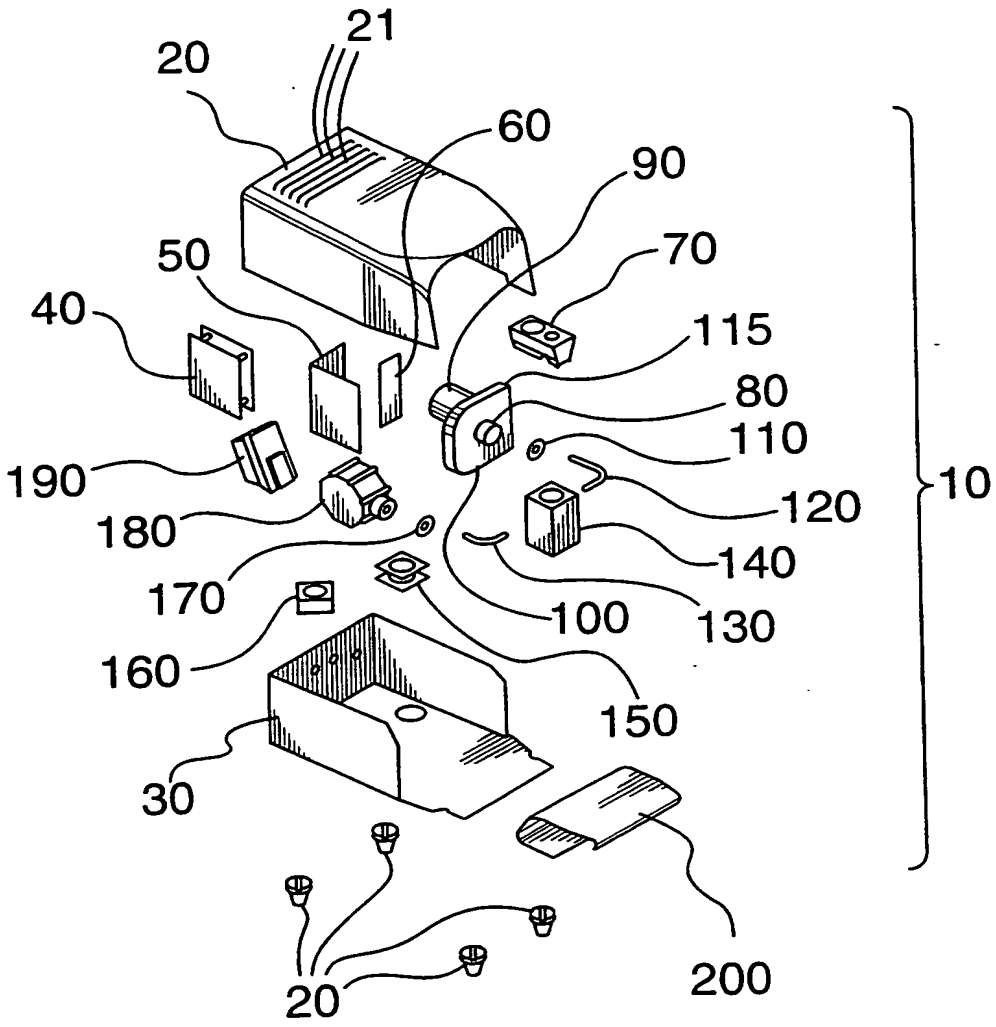

21
20
60
90
70
50
40
115
80
110
190
120
10
180
140
170
100
130
160
150
30
200
20

FIGURE 3B

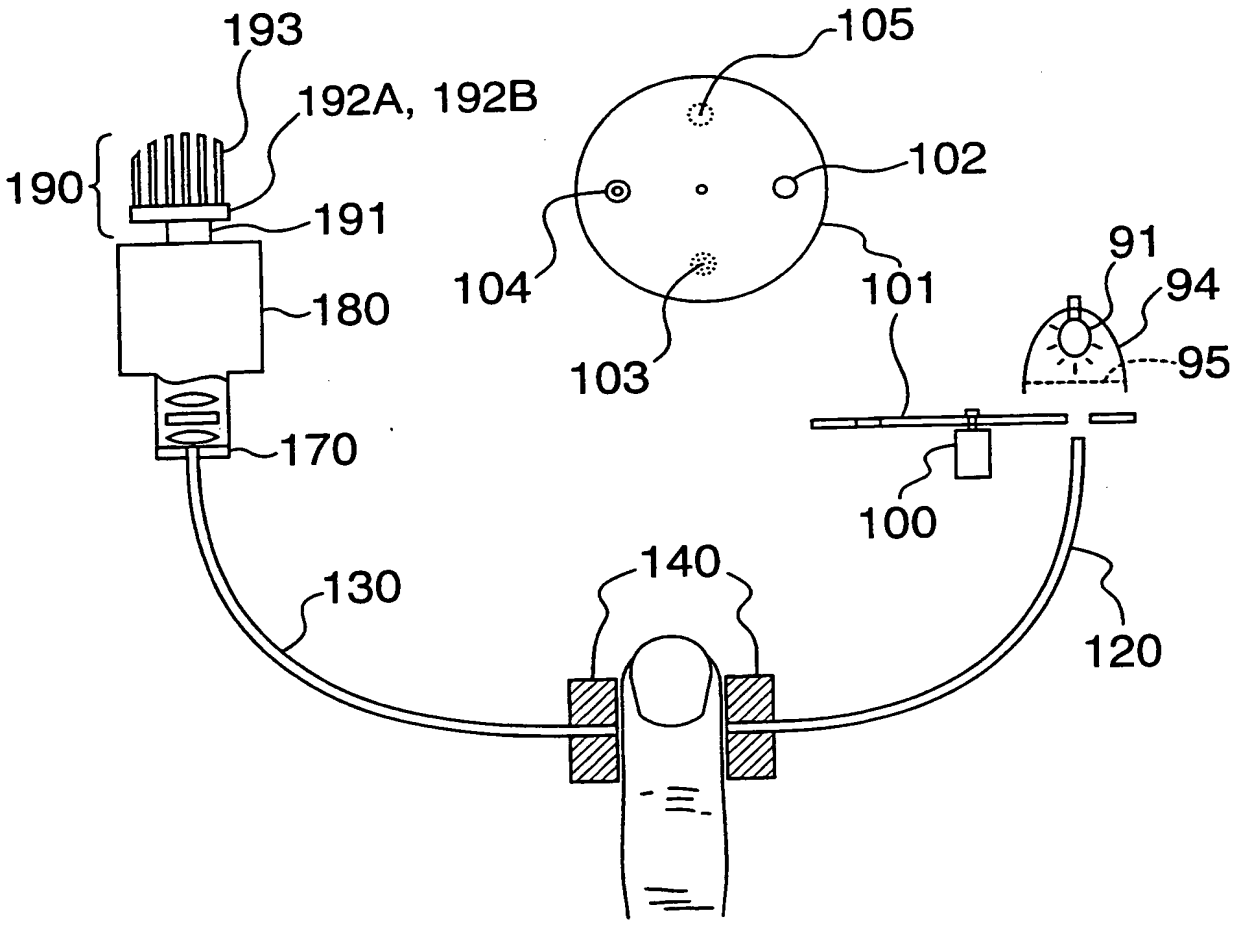

193
192A, 192B
190
191
180
170
130
105
102
104
101
103
91
94
95
100
140
120

FIGURE 3C

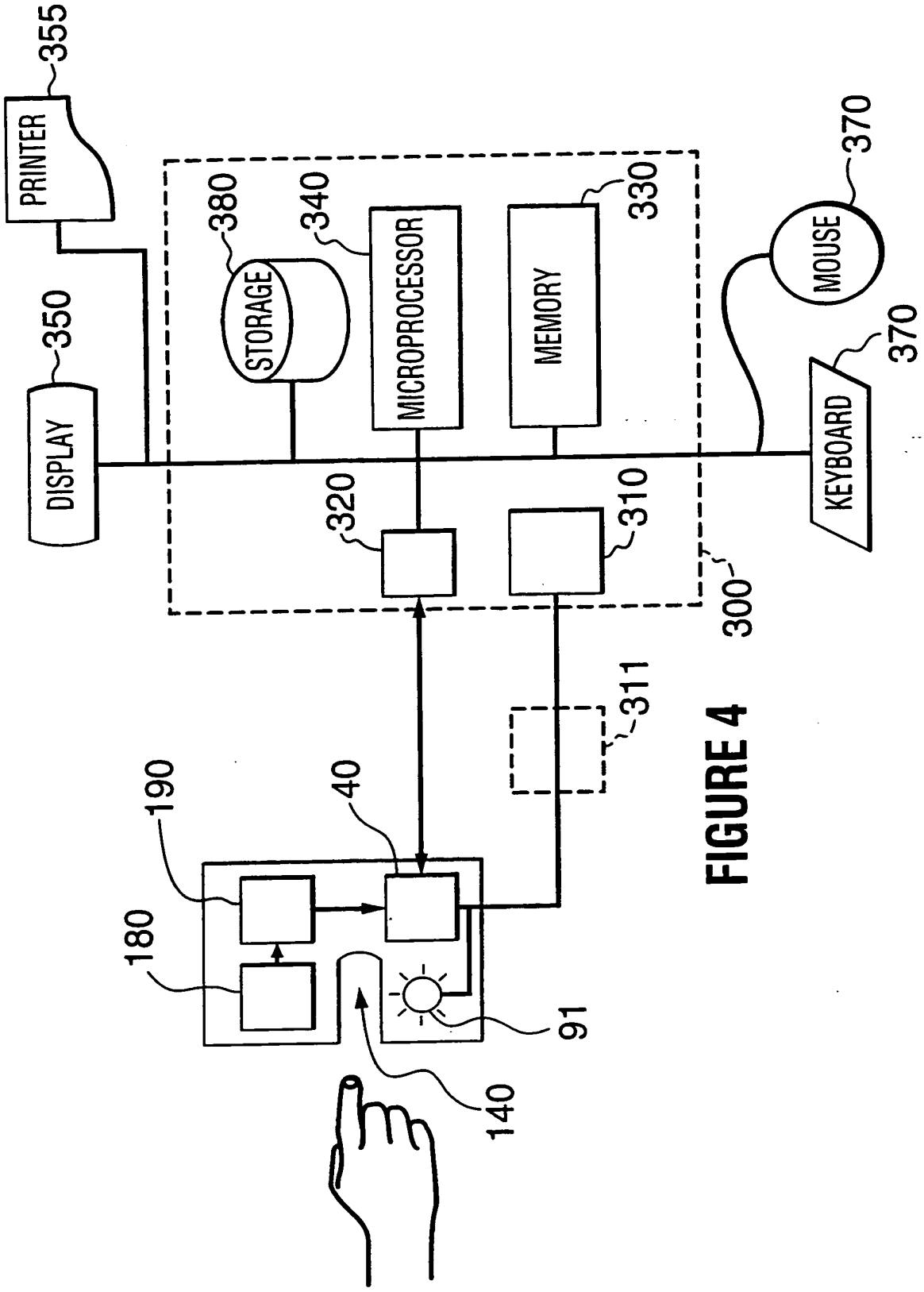

355
PRINTER
350
DISPLAY
380
STORAGE
340
MICROPROCESSOR
330
MEMORY
370
MOUSE
370
KEYBOARD
320
310
300
311
190
40
180
91
140

FIGURE 4

INTERNATIONAL SEARCH REPORT

Inter[illegible]pplication No
PCT/CA 00/01004

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 G01N21/31 G01N21/35

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 361 758 A (HALL JEFFREY W ET AL) 8 November 1994 (1994-11-08) cited in the application column 3, line 52 -column 4, line 58; figure 1	1,5,6,8, 9
A	US 5 429 128 A (CADELL THEODORE E ET AL) 4 July 1995 (1995-07-04) cited in the application column 2, line 4-21 column 3, line 28-53; figure 1	1,8,10
A	US 5 086 229 A (MACKIE LINDA H ET AL) 4 February 1992 (1992-02-04) column 2, line 51-61 column 4, line 41 -column 6, line 16 column 7, line 1 -column 8, line 19 column 14, line 6-55; figures 2A,2B,19	1-3,7,8

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 December 2000	05/01/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Meyer, F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 00/01004

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 167 230 A (CHANCE BRITTON) 1 December 1992 (1992-12-01) column 2, line 38-65 column 3, line 41 -column 5, line 4 column 5, line 59-63; figures 2,3 abstract	1
A	WO 92 00513 A (FUTREX INC) 9 January 1992 (1992-01-09) page 40, line 26 -page 42, line 13; figure 21	1,2,5-7

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATION[redacted] SEARCH REPORT

..formation on patent family members

Inter[redacted]plication No
PCT/CA 00/01004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5361758 A	08-11-1994	NONE	
US 5429128 A	04-07-1995	AU 8411691 A	30-03-1992
		WO 9203965 A	19-03-1992
		EP 0545987 A	16-06-1993
		JP 6503728 T	28-04-1994
		DE 69117517 D	04-04-1996
		DE 69117517 T	12-09-1996
US 5086229 A	04-02-1992	US 5028787 A	02-07-1991
		AT 145988 T	15-12-1996
		AU 8238791 A	23-01-1992
		CA 2086019 A,C	28-12-1991
		DE 69123448 D	16-01-1997
		DE 69123448 T	22-05-1997
		EP 0536304 A	14-04-1993
		IE 77034 B	19-11-1997
		JP 5508336 T	25-11-1993
		NZ 238717 A	26-08-1994
		US 5576544 A	19-11-1996
		WO 9200513 A	09-01-1992
		US 5362966 A	08-11-1994
		US 5436455 A	25-07-1995
		US 6066847 A	23-05-2000
		US 5438201 A	01-08-1995
		US 5574283 A	12-11-1996
		US 5077476 A	31-12-1991
		US 5204532 A	20-04-1993
		US 5218207 A	08-06-1993
		US 5237178 A	17-08-1993
		US 5365066 A	15-11-1994
		ZA 9104977 A	29-04-1992
		AT 163844 T	15-03-1998
		AU 5042190 A	13-08-1990
		CA 2045599 A,C	20-07-1990
		DE 69032126 D	16-04-1998
		DE 69032126 T	15-10-1998
		EP 0456716 A	21-11-1991
		ES 2114860 T	16-06-1998
		JP 2191434 A	27-07-1990
		JP 5058735 B	27-08-1993
		KR 145695 B	01-08-1998
		WO 9007905 A	26-07-1990
		US 5068536 A	26-11-1991
US 5167230 A	01-12-1992	CA 1331483 A	16-08-1994
		DE 68928348 D	30-10-1997
		DE 68928348 T	16-04-1998
		EP 0441791 A	21-08-1991
		JP 2603350 B	23-04-1997
		JP 4502563 T	14-05-1992
		WO 9004941 A	17-05-1990
		US 5779631 A	14-07-1998
		US 6134460 A	17-10-2000
WO 9200513 A	09-01-1992	US 5086229 A	04-02-1992
		US 5077476 A	31-12-1991
		US 5068536 A	26-11-1991

INTERNATIONAL SEARCH REPORT

..formation on patent family members

Inter...nal Application No
PCT/CA 00/01004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9200513 A		AT 145988 T	15-12-1996
		AU 8238791 A	23-01-1992
		CA 2086019 A,C	28-12-1991
		DE 69123448 D	16-01-1997
		DE 69123448 T	22-05-1997
		EP 0536304 A	14-04-1993
		IE 77034 B	19-11-1997
		JP 5508336 T	25-11-1993
		NZ 238717 A	26-08-1994
		US 5576544 A	19-11-1996
		US 5362966 A	08-11-1994
		US 5436455 A	25-07-1995
		US 6066847 A	23-05-2000
		US 5438201 A	01-08-1995
		US 5574283 A	12-11-1996
		US 5204532 A	20-04-1993
		US 5218207 A	08-06-1993
		US 5237178 A	17-08-1993
		US 5365066 A	15-11-1994
		ZA 9104977 A	29-04-1992